



'99 MM 23 P2:16 1297

March 15, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204



Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement within the last thirty days under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

Black Cohosh: Natural support for menopause. Black Cohosh root is a popular choice to help support women's special needs and bring balance during menopause. Most women notice an improved sense of well-being within four to eight weeks of using Black Cohosh as directed. To further support women's special needs, take this product with Sundown Soy Isoflavones and Sundown Chasteberry. Soy, a staple of the Asian diet for thousands of years, provides nutritional support during menopause. Chasteberry contains compounds that help to promote balance in a woman's monthly cycle and may also provide natural support for menopause.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Vice President of Regulatory Affairs

and Assistant General Counsel

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Enclosure